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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,491	04/22/2004	Ing-Ming Chiu	28489/04001	7628
24024	7590	11/17/2004	EXAMINER	
CALFEE HALTER & GRISWOLD, LLP 800 SUPERIOR AVENUE SUITE 1400 CLEVELAND, OH 44114			ALONZO, NORMA LYN	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/829,491	CHIU, ING-MING	
	Examiner	Art Unit	
	Norma C Alonzo	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 1-36 are pending in the instant specification.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, 15-33, drawn to a non-human transgenic mammal whose genome comprises a transgene comprising a promoter comprising the nuclear factor binding region of the RR2 cis acting element of an GFG1B promoter, and a DNA fragment comprising a sequence encoding the SV40 large T antigen, a cell line derived from said mammal, and an *in vivo* method for using said mammal for identifying a drug which is effective at inhibiting the growth of brain tumors in a mammal, classified in class 800, subclass 9.
- II. Claims 12-14, drawn to a DNA construct comprising an active portion of the FGF1B promoter operably linked to a sequence encoding the SV40 large T antigen, classified in class 435, subclass 320.1.
- III. Claims 34-36, drawn to a method for obtaining neural stem cells from a population of cells obtained from an animal, classified in class 435, subclass 378.

The inventions are distinct, each from the other because of the following reasons:

2. The inventions of Group I and II are patentably distinct. Whereas the inventions are related as comprising a promoter comprising an element of the FGF1B promoter and a sequence encoding the SV40 large T antigen, the inventions are drawn to compositions having a distinct structure, function and utility. For example, the non-human transgenic mammal of Group I is patentably distinct from the DNA construct of Group II. Therefore, because the inventions are different, each from the other, they are patentably distinct and will require a separate search in the patent and non-patent literature.

4. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Group I is drawn to a non-human transgenic mammal having cells comprising a FGF1B-detector transgene, a cell line derived from said mammal and a method for using said mammal and Group IV is drawn to a method for obtain neural stem cells from a population of cells obtained from an animal comprising incorporating an FGF1B-detector transgene. Whereas the non-human transgenic mammal of group I could be used in the method of Group III, said mammal could be used in a method for screening compounds useful in the treatment of brain tumors. Similarly, the method of Group III could use cells from a

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non-transgenic animal, wherein said cells are transfected with a vector comprising an FGF1B-detector transgene. Therefore, because the inventions are different, each from the other, they are patentably distinct and will require a separate search in the patent and non-patent literature.

6. Inventions II and III are patentably distinct. Group II is drawn to a DNA construct, whereas Group III is drawn to a method for obtaining neural stem cells from a population of cells obtained from an animal. The groups are drawn to inventions having different physical structure, function and utility and further, the DNA construct of Group II cannot be used in the method of Group III. Therefore, because the inventions are different, each from the other, they are patentably distinct and will require a separate search in the patent and non-patent literature.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Norma C Alonzo whose telephone number is 571-272-2910. The examiner can normally be reached on 8-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NCA


RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER